



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA), Office of the Commissioner (OC), Office of the Chief Scientist (OCS) has modified their organizational structure. The new organizational structure was approved by the Deputy Secretary of Health and Human Services and effective on November 24, 2021.

FOR FURTHER INFORMATION CONTACT: Yashika Rahaman, Director, Office of Planning, Evaluation and Risk Management, Office of Finance, Budget, Acquisitions and Planning, FDA, 4041 Powder Mill Road, Beltsville, MD, 20705-4304, 301-796-3843.

I. Introduction

Part D, Chapter D-B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is revised to reflect the Food and Drug Administration's reorganization of Office of the Chief Scientist.

The FDA Office of the Commissioner, Office of the Chief Scientist (OCS), is realigning the FDA Technology Transfer Program (FDATT), from the Office of Regulatory Science and

Innovation (ORSI), OCS, to the OCS Immediate Office (OCS-IO). This realignment of the FDATT program and resources intends to further enhance the effectiveness of FDA's partnership programs by increasing the FDA-wide impact of FDATT's leadership in its efforts to 1) facilitate the implementation of authorizing legislation for federal technology transfer, 2) ensure compliance with relevant legal and regulatory requirements, and 3) establish/maintain related policies and processes. The realignment will also increase OCS's effectiveness in driving regulatory science research through external partnerships and would demonstrate FDA's commitment to strengthening its partnership and collaboration capabilities, which are key contributors to sustaining FDA's ability to see and be at the forefront of biomedical advancements in carrying out its public health mission. Additionally, OCS is abolishing the Division of Science Innovation & Critical Path from its Office of Regulatory Science and Innovation (ORSI). ORSI's programs have evolved away from the need for this division. This proposed, formal abolishment of the division will serve as a corrective action to align ORSI's organizational structure with its current programmatic responsibilities that fulfill its functions. The Food and Drug Administration's Office of the Chief Scientist has been restructured as follows:

DCCF. ORGANIZATION. The Office of the Chief Scientist is headed by the FDA Chief Scientist, and includes the following:

Office of the Chief Scientist (DCP)

Advisory Committee Oversight and Management Staff (DCP1)

FDA Technology Transfer Program Staff (DCP2)

Office of Counter-Terrorism and Emerging Threats (DCPA)

Office of Laboratory Safety (DCPB)

Office of Regulatory Science and Innovation (DCPC)

Office of Scientific Integrity (DCPD)

Office of Scientific Professional Development (DCPE)

National Center for Toxicological Research (DCPF)

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete Staff Manual Guide can find it on FDA's website at:

<https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm>

Authority: 44 U.S.C. 3101

Dated: October 22, 2021.

Andrea Palm,

Deputy Secretary of Health and Human Services.